Remarks

A. Pending Claims

Claims 1-2, 5-6, 8-28, 53, 75, and 140 have been rejected. Claims 1-2, 5-6, 8-28, 53, 75, 97, 116, and 140 are currently pending.

B. The Claims Are Not Anticipated By Khairkhahan Pursuant To 35 U.S.C. § 102(e)

Claims 1-2, 5-6, 8-26, 28, 53, and 140 were rejected pursuant to 35 U.S.C. §102 (e) as being anticipated by U.S. Patent Application Publication No. 2002/0111647 A1 to Khairkhahan et al. (herein after "Khairkhahan"). Applicant respectfully disagrees.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed. Cir. 1986); In re Donahue, 766 F.2d 531,226 U.S.P.Q. 619,621 (Fed. Cir. 1985).

The Office Action states:

> With regard to claims 1, 5, and 15 Khairkhahan discloses an apparatus comprising a reinforcing element (11) configured to reinforce a portion of an endocardial surface (see entire document; Figure 1). The element (11) is movable between a reduced, first predetermined shape and an expanded, second predetermined shape ([0060]). An adjustment mechanism is utilized to expand the device while in a patient's body so that the reinforcing element is configured to change from the first shape to the second while in a ventricle of the patient's heart ([00796]). The adjustment mechanism is further disclosed as a pullwire that is activated by a user ([0076]). Therefore, there inherently exists an infinite number of cross-sectional profiles of the reinforcing element between the fully reduced, first predetermined shape and the fully expanded, second predetermined shape so that user is able to adjust the adjustment mechanism to a third shape.

> Although Khairkhahan does not specifically disclose the reinforcing element for use in an endocardial surface of a ventricle, specifically scar tissue, this is an intended use phrase and therefore given minimal patentable weight. The examiner's position is supported by law, which holds that "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) and MPEP 2111.02.

Applicant respectfully submits that Khairkhahan does not appear to teach or suggest the combination of features in claims 1-2, 5-6, 8-26, 28, 53, and 140.

As for the Office Action's assertion that their position is supported by law, specifically referencing *Rowe v. Dror*, Applicants respectfully submits that *Rowe v. Dror* specifically relates to the extent to which the preamble of a claim should be given weight during prosecution. Applicant submits that Applicant has yet to rely on the preamble of any of the current claims in refuting the rejections in the Office Action, and specifically has cited passages in the claim body of the current claim. Applicant therefore respectfully fails to see the relevance of *Rowe v. Dror*.

Throughout the Office Action the Examiner asserts that the use of "configured to" in the claims "is an intended use phrase and therefore given minimal patentable weight." However, the "configured to" limitations in Applicants' claims require various properties or functional capabilities. The Examiner cites *In re Hutchinson*, 154 F.2d 135, 69 USPQ 138 (CCPA 1946). Various other decisions, some of which are discussed below, hold that such claim limitations do have patentable weight in that they impose capability requirements. In other words, the limitation distinguishes over the prior art if the prior art does not teach a structure having the same capability recited in the claim. Accordingly, these decisions have held that "configured to" limitations cannot be ignored.

Various instances of "configured to" in Applicants' claims accompany language that recites specific limitations of the corresponding element. In other words, the claims describe that the claim elements are physically configured to perform a certain function

or have certain properties. As acknowledged by the Examiner, a "configured to" limitation at least requires the ability to perform the stated function. Thus, to anticipate such a limitation the prior art would have to describe an object that at least had the same ability. The use of functional limitations to define an invention has been expressly approved by the courts. *See, e.g., In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). In fact, the Court has held that a functional claim limitation can distinguish over the prior art "because it set definite boundaries on the patent protection sought." *In re Barr*, 444 F.2d 588, 170 USPQ 33 (CCPA 1971). Moreover, the Court has held that limitations using "configured to" or "adapted to" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly. *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976). Applicants also refer the Examiner to the claim construction using "configured to" limitations in *State Street Bank & Trust Co. v. Signature Financial Group Inc.,* 47 USPQ2d 1596 (Fed. Cir. 1998). Therefore, the Examiner's position that such limitations have no patentable weight is simply not correct.

Claim 1 describes a combination of features including, but not limited to, the feature of: "wherein the second predetermined shape is configured to reinforce at least a portion of an endocardial surface of a ventricle of the human heart during use such that the portion of the endocardial surface is inhibited from expanding while still allowing normal contraction and expansion during a cardiac cycle of the heart."

Claim 28 describes a combination of features including, but not limited to, the feature of: "wherein the reinforcing element is configured to attach to a portion of an endocardial surface of the heart to inhibit expansion of an average of an endocardial surface over a cardiac cycle of the heart, while still allowing normal contraction and expansion of the heart during a cardiac cycle."

Claim 53 describes a combination of features including, but not limited to, the feature of: "wherein the reinforcing element is configured to inhibit expansion of an average of an endocardial surface over a cardiac cycle of the heart during use, while still allowing normal contraction and expansion of the heart during a cardiac cycle."

Khairkhahan discloses:

> [0059] In use, the occlusion device 10 is preferably positioned within a tubular anatomical structure to be occluded such as the left atrial appendage. In a left atrial appendage application, the occluding member 11 is positioned across or near the opening to the LAA and the stabilizer 194 is positioned within the LAA. The stabilizer 194 assists in the proper location and orientation of the occluding member 11, as well as resists compression of the LAA behind the occluding member 11. The present inventors have determined that following deployment of an occluding member 11 without a stabilizer 194 or other bulking structure to resist compression of the LAA, normal operation of the heart may cause compression and resulting volume changes in the LAA, thereby forcing fluid past the occluding member 11 and inhibiting or preventing a complete seal. Provision of a stabilizer 194 dimensioned to prevent the collapse or pumping of the LAA thus minimizes leakage, and provision of the barbs facilitates endothelialization or other cell growth across the occluding member 11.
> [0060] The stabilizer 194 is preferably movable between a reduced cross-sectional profile for transluminal advancement into the left atrial appendage, and an enlarged cross-sectional orientation as illustrated to fill or to substantially fill a cross-section through the LAA. The stabilizing member may enlarge to a greater cross section than the (pre-stretched) anatomical cavity, to ensure a tight fit and minimize the likelihood of compression. One convenient construction includes a plurality of elements 196 which are radially outwardly expandable in response to axial compression of a distal hub 191 towards a proximal hub 16. Elements 196 each comprise a distal segment 198 and a proximal segment 202 connected by a bend 200. The elements 196 may be provided with a bias in the direction of the radially enlarged orientation as illustrated in FIG. 2, or may be radially expanded by applying an expansion force such as an axially compressive force between distal hub 191 and proximal hub 16 or a radial expansion force such as might be applied by an inflatable balloon. Elements 196 may conveniently be formed by laser cutting the same tube stock as utilized to construct the distal hub 191, proximal hub 16 and frame 14, as will be apparent to those of skill in the art in view of the disclosure herein. Alternatively, the various components of the occlusion device 10 may be separately fabricated or fabricated in subassemblies and secured together during manufacturing. (Khairkhahan, page 4).

Khairkhahan appears to teach or suggest an occlusion device which functions to resist compression and prevent the collapse of a tubular anatomical structure wherein the occlusion

device is positioned. Khairkhahan does not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein the second predetermined shape is configured to reinforce at least a portion of an endocardial surface of a ventricle of the human heart during use such that the portion of the endocardial surface is inhibited from expanding while still allowing normal contraction and expansion during a cardiac cycle of the heart," or "wherein the reinforcing element is configured to attach to a portion of an endocardial surface of the heart to inhibit expansion of an average of an endocardial surface over a cardiac cycle of the heart, while still allowing normal contraction and expansion of the heart during a cardiac cycle," or "wherein the reinforcing element comprises: a plurality of conduits that form the predetermined shape during use; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit when activated to engage the portion of the endocardial surface."

The Office Action further states:

> With regard to claims 16, 26, 28, and 53 the frame (14) comprises metal spokes (17), which overlap the instantly claimed plurality of conduits ([0044]; Figure 1). Anchors (195) are attached to the spokes and extend distally beyond the conduits ([0055]; [0057]).

Claim 16 describes a combination of features including, but not limited to, the feature of: "a plurality of conduits that form the first predetermined shape, the second predetermined shape, or the first predetermined shape and the second predetermined shape; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit and to engage the portion of the endocardial surface when activated."

Claim 28 describes a combination of features including, but not limited to, the feature of: "a plurality of conduits that form the first predetermined shape, the second predetermined shape, or the first predetermined shape and the second predetermined

shape; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit and to engage the portion of the endocardial surface when activated."

Claim 53 describes a combination of features including, but not limited to, the feature of: "wherein the reinforcing element comprises: a plurality of conduits that form the predetermined shape during use; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit when activated to engage the portion of the endocardial surface."

Khairkhahan discloses:

> [0044] The occlusion device 10 comprises an occluding member 11 comprising a frame 14 and a barrier 15. In the illustrated embodiment, the frame 14 comprises a plurality of radially outwardly extending spokes 17 each having a length within the range of from about 0.5 cm to about 2 cm from a hub 16. In one embodiment, the spokes have an axial length of about 1.5 cm. Depending upon the desired introduction crossing profile of the collapsed occlusion device 10, as well as structural strength requirements in the deployed device, anywhere within the range of from about 3 spokes to about 40 spokes may be utilized. In some embodiments, anywhere from about 12 to about 24 spokes are utilized, and, 18 spokes are utilized in one embodiment. (Khairkhahan, page 3).
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> [0055] Preferably, the occlusion device 10 is provided with one or more retention structures for retaining the device in the left atrial appendage or other body cavity or lumen. In the illustrated embodiment, a plurality of barbs or other anchors 195 are provided, for engaging adjacent tissue to retain the occlusion device 10 in its implanted position and to limit relative movement between the tissue and the occlusion device. The illustrated anchors are provided on one or more of the spokes 17, or other portion of frame 14. Preferably, every spoke, every second spoke or every third spoke are provided with one or two or more anchors each. (Khairkhahan, page 4).
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> [0057] Alternatively, one or more barbs may face distally, to inhibit distal migration of the occlusion device deeper into the LAA. Thus the implant

may be provided with at least one proximally facing barb and at least one distally facing barb. For example, in an embodiment of the type illustrated in FIG. 12, discussed below, a proximal plurality of barbs may be inclined in a first direction, and a distal plurality of barbs may be inclined in a second direction, to anchor the implant against both proximal and distal migration. (Khairkhahan, page 4).

Applicant's specification states:

In some embodiments, a coupling mechanism may include a plurality of elongated members 912, as depicted in FIG. 14. FIG. 14 does not depict a plurality of conduits 910 for purposes of clarity. Elongated members 912 may be at least in part formed from shape memory metals (e.g., nitinol). In some embodiments, elongated members 912 may include pointed, sharp, and/or needle tipped distal ends 914. Elongated members 912 may be positioned in conduits 910 (depicted in FIG. 13). One or more elongated members may be positioned in the conduits. In certain embodiments, only one elongated member may be positioned in each conduit. When in a retracted or inactivated state, at least distal ends 914 may be positioned substantially in conduits 910. When in an extended or activated state, at least distal ends 914 may be extended substantially beyond the distal end of each respective conduit 910. Distal ends 914 of elongated members 912 may be predisposed (e.g., preshaped in the case of shape memory metal based elongated members) to exist in a substantially inwardly curled state as depicted in FIG. 14. FIG. 15 depicts reinforcing element 908 with distal ends 914 of the elongated members activated and extended from conduits 910.

FIG. 16 depicts a cross sectional view of a portion of reinforcing element 908, including one conduit 910 and one elongated member 912. Elongated member 912 is depicted in a retracted/inactivated state in FIG. 16. Elongated member 912 may be formed from a substantially flexible material such that the distal end 914 may bend and flex so as to be positionable in conduit 910 when in a retracted state. When elongated member 912 is in an extended/activated state distal end 914 may change shape to a substantially inwardly curled state (as depicted in FIG. 17). Distal ends 914 in the substantially curled state may pierce tissue (when positioned in a portion of a heart) attaching reinforcing element 908 to the portion of the heart. (Application, page 30, lines 2-26).

Applicant (e.g., claim 16) describes a combination of features including, but not limited to, the feature of: "at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at

least partially extend beyond a distal end of the corresponding conduit and to engage the portion of the endocardial surface when activated." A non-limiting example of the claimed feature(s) cited is disclosed in the specification on page 30, lines 2-26 (quoted herein above), along with the corresponding figures (FIGS. 14-17). A "conduit" is generally defined as "A tube or duct for enclosing electric wires or cable." (See The American Heritage® Dictionary of the English Language, Fourth Edition). Khairkhahan does not appear to teach or suggest an elongated member positionable inside of a conduit, wherein the elongated member is extendable out of a distal end of the conduit such that the elongated member engages an endocardial surface. Khairkhahan does not appear to teach or suggest using any type of conduit for constructing his occlusion device. Khairkhahan disclosed occlusion device is structurally different from Applicant's currently claimed apparatus for reinforcing at least a portion of an endocardial surface of a ventricle in a human heart.

Applicant submits, that many of the claims dependent on claim 1 are separately patentable. At least a few of the separately patentable dependent claims are listed below by way of example.

The Office Action states:

> With regard to claim 140, as shown in Figure 1, the shape of the reinforcing member is similar to a shape and size of a portion of the left ventricle.

Claim 140 includes, but is not limited to, the feature of: "wherein the third shape is similar to a shape and size of at least a portion of an appropriate left ventricle." The features of claim 140, in combination with the features of independent claim 1, do not appear to be taught or suggested by the prior art.

The specification discloses:

> In some embodiments, a shaping device may be pre-shaped to generally model the appropriate volume and shape of the left ventricle, as is depicted in FIG. 2a. Shaping device 200 may be used as a guide in reforming the left ventricle so that the reconstructed heart may be formed closer to the size and shape of the pre-enlarged heart. Consequently, the heart performs better post operatively than with conventional methods. As illustrated in FIG. 2a, shaping device 200 may be conical or "tear drop" in shape. The length of shaping device 200 may vary with each patient and will typically be a function of the volume selected for the shaping device. The size, shape, and/or volume of shaping device 200 may vary according to individual patient specific needs. Shaping device 200 may be designed and manufactured for a specific patient's needs. In some embodiments, shaping device 200 may be manufactured in a variety of sizes, shapes, and/or volumes, from which a user may select an appropriate shaping device for a specific patient. Depending on the patient, the length may be between about three inches to about four inches to generally match the length of the pre-enlarged left ventricle. A doctor may select the appropriate volume for the shaping device by estimating the volume of the pre-enlarged left ventricle. Such selection procedures and shaping devices are discussed in U.S. patent application serial no. 09/864,510, filed on May 24, 2001 by the inventors, which is hereby incorporated by reference into this application.

Khairkhahan appears to teach or suggest an occlusion device which functions to resist compression and prevent the collapse of a **tubular** anatomical structure wherein the occlusion device is positioned. Khairkhahan does not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein the third shape is similar to a shape and size of at least a portion of an appropriate left ventricle."

Applicant requests removal of the anticipation rejection of claims 1-2, 5-6, 8-26, 28, 53, and 140.

C. The Claims Are Not Obvious Over Khairkhahan Pursuant To 35 U.S.C. § 103(a)

Claims 27 and 75 were rejected under 35 U.S.C. 103(a) as obvious over Khairkhahan. Applicant respectfully disagrees with the rejection.

In order to reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177-178 (C.C.P.A. 1967). To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP § 2143.03.

The Office Action states:

> Khairkhahan discloses a reinforcing element for reinforcing a portion of a patient's heart. As shown in Figure 19, the apparatus comprises a lumen (322) for positioning a guidewire ([0083]; Figure 19). Although the guidewire, does not extend beyond the distal end of the reinforcing element, this limitation would have been obvious at the time of the invention. It is well known in the art for guidewires to extend beyond the distal end of devices when inserted into a patient's vasculature to facilitate entry into the curving vasculature. Additionally, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the apparatus. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Applicant respectfully submits that Khairkhahan does not appear to teach or suggest the combination of features in claims 27 and 75.

Claim 27 describes a combination of features including, but not limited to, the feature of: "wherein the guidewire is configured to releasably attach to an endocardial surface of the heart."

Claim 75 describes a combination of features including, but not limited to, the feature of: "wherein the guidewire is configured to releasably attach to an endocardial surface of the heart."

Applicant respectfully suggests that the Office Action has merely commented on guidewires extending beyond the distal end of the reinforcing element (which the Office

Action admits is not disclosed by Khairkhahan), but does not comment on other feature(s) within the rejected claims 27 and 75. Khairkhahan does not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein the guidewire is configured to releasably attach to an endocardial surface of the heart."

In addition, portions of the aforementioned rejection appears to be set forth in facts within the personal knowledge of the Examiner and therefore Applicant believes MPEP 2144.03 will apply. Pursuant to MPEP 2144.03, Applicant respectfully requests the Examiner to provide support for his assertion either by an affidavit or by references brought to the Applicant's attention. Otherwise, Applicants request this rejection be removed. *See, e.g.*, MPEP 2143.01

Applicant requests removal of the obviousness rejection of claims 27 and 75.

D. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

Applicant respectfully requests a three-month extension of time. If any further extension of time is required, Applicant hereby requests the appropriate extension of time. Applicant has submitted a fee authorization form for fees associated with a three-month extension of time. If any further fees are required, or have been overpaid, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5838-01801/EBM.

Respectfully submitted,

Eric B. Meyertons
Reg. No. 34,876

Attorney for Applicant

MEYERTONS, HOOD, KIVLIN, KOWERT & GOETZEL, P.C.
P.O. BOX 398
AUSTIN, TX 78767-0398
(512) 853-8800 (voice)
(512) 853-8801 (facsimile)

Date: 4/9/09